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| 09/808,375 | 03/14/2001 | Shaorong Liu | PB0006 | 3335 |

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| EXAMINER | |
|---|---|
| NOGUEROLA, ALEXANDER STEPHAN | |
| ART UNIT | PAPER NUMBER |
| 1753 | |

DATE MAILED: 10/28/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

A2-8

| Office Action Summary | Application No. 09/808,375 | Applicant(s) LIU, SHAORONG |
|---|---|---|
| | Examiner ALEX NOGUEROLA | Art Unit 1753 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-16,18 and 20* is/are rejected.

7)☒ Claim(s) *8,9,17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

***Response to Arguments***

1. Applicant's arguments filed August 06, 2003 have been fully considered but they are not persuasive. With respect to the rejection of claims 1 and 10 under 35 U.S.C. 102(b), page 9 of Applicant's amendment, bridging to page 10, states,

> 'Applicant submits that Manz does not teach, or even suggest, a shaped microfabricated capillary array electrophoresis chip having a first major surface defining converging first and second elongate separate channels. Further, since Manz does not teach "a shaped capillary electrophoresis chip having a first major surface, converging first and second elongate separation channels, and first and second perimetrical edge segments," Applicants respectfully submits that claim 10 [and presumably claim 1] is not anticipated by Manz.'

The examiner's rejection of claims 1 and 10 under 35 U.S.C. 102(b) is detailed. In the rejection every feature claimed by Applicant has been identified in Manz's disclosure. Applicant is invited to specifically indicate which claimed feature(s) is not disclosed by Manz or has been incorrectly identified in the rejection as being taught by Manz.

***Status of the Objections and Rejections Pending since the Office action of May 06, 2003***

2. The objections to the drawings are withdrawn.

3. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, is withdrawn.

4. The rejection of claims 1 and 10 under 35 U.S.C. 102(b) as being anticipated by Manz is maintained.

5. The rejection of claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Zanzucchi in view of Roach is withdrawn .

***Claim Rejections - 35 USC § 102***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-7 and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz (US 5,296,114).

Addressing claims 1 and 10, Manz teaches a shaped microfabricated capillary array electrophoresis chip (the abstract; Figure 1; and col. 4, ll. 14-16) comprising

a planar substrate (element 1 in Figure 1) having a first major surface defining converging first and second elongate separate channels (any pair of intersecting channel sections, such as, 5 and 6 or 8 and 7), wherein each separation channel section extends between an associated cathode port and an anode port defined by the first major surface (at the end of each channel section is one of the electrode ports 20-27), wherein the substrate further comprises a first perimetrical edge segment extending substantially along the first separation channel section;

and a second perimetrical edge segment extending substantially along the second separation channel section (as seen in Figure 1 each channel section is close to and parallel to an edge of the chip).

Note that Manz teaches that the chip does not have to be rectangular; he teaches a general n-sized figure, which preferably has at least three sides (col. 6, ll. 38-46).

For claim 10 note that since Manz teach a shaped capillary electrophoresis chip having a first major surface, converging first and second elongate separation channels, and first and second perimetrical edge segments as claimed, they must have been provided or formed.

Addressing claim 2, Figures 3 and 4 show a common anode port for the separation channels.

Addressing claims 3 and 15, an inlet port and an outlet port for each separation channel is taught by Figure 1 and col. 6, ll. 18.

Addressing claims 4 and 16, as seen in Figure 1 all the separation channels extend linearly.

Addressing claims 5, 6, 11, and 12, as seen in Figure 1 the perimetrical edges are 90 degrees with respect to each other. Also, note again that Manz teaches that the chip does not have to be rectangular; he teaches a general n-sized figure, which preferably has at least three sides (col. 6, ll. 38-46).

Addressing claim 7, Figure 1 shows a cathode in fluid communication with a pair of separation channels.

Addressing claims 13 and 14, Figures 3 and 4 show a separation channel 8, for example, extending between anode U+ and cathode U-. Note that although only two electrodes are shown in Figures 3 and 4, Manz clearly teaches an electrode at each end of each separation channel (Figures 3-8 cumulatively and col. 5, ll. 5-15).

***Claim Rejections - 35 USC § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manz (US 5,296,114).

Manz teaches a shaped microfabricated capillary array electrophoresis chip (the abstract; Figure 1; and col. 4, ll. 14-16) comprising

a planar substrate (element 1 in Figure 1) having a first major surface defining converging first and second elongate separate channels (any pair of intersecting channel sections, such as, 5 and 6 or 8 and 7), wherein each separation channel section extends between an associated cathode port and an anode port defined by the first major surface (at the end of each

channel section is one of the electrode ports 20-27), wherein the substrate further comprises a first perimetrical edge segment extending substantially along the first separation channel section; and a second perimetrical edge segment extending substantially along the second separation channel section (as seen in Figure 1 each channel section is close to and parallel to an edge of the chip).

Note that Manz teaches that the chip does not have to be rectangular; he teaches a general n-sized figure, which preferably has at least three sides (col. 6, ll. 38-46).

Although Manz does not mention a second chip having the features of the chip described above, this is mere duplication of parts, which has been held obvious. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide two or more chips so that electrophoresis separations on two or more samples can be simultaneously performed. As for the limitation of the first chip cooperatively engaging the second chip this appears to only mean that the chips can be placed side-by-side flush one against the other (Figure 4 and the last paragraph on page 6 of Applicant's specification). The chip embodiment shown in Figure 1 of Manz would cooperatively engage another such chip.

***Allowable Subject Matter***

10. Claims 8, 9, 17, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 8 requires a grouped pair of elongate separation channels extending in fluid communication between a common cathode port and anode port and having a loading segment;

b) Claim 9 depends from allowable claim 8;

c) Claim 17 requires forming a grouped pair of elongate separation channels extending in fluid communication between a common cathode port and anode port and having a loading segment;

d) Claim 18 depends from allowable claim 17; and

e) Claim 19 requires forming 48 converging channels in the first major surface.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola
Alex Noguerola
10/24/03
Primary Examiner
TC 1753